REMARKS

This is a full and timely response to the outstanding final Office Action mailed October 1, 2010. Claims 1-5, 9, and 11-13 are pending in the present application. Through this response, claims 1 and 9 have been amended and claims 10-11 have been canceled without prejudice, waiver, or disclaimer. Reconsideration and allowance of the application and pending claims are respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 5, and 11-13 have been rejected under 35 U.S.C. 102(b) as being anticipated by *Gupta et al* (Kidney International 1999, 55, 1891-1898, hereinafter "*Gupta*"). Applicants respectfully traverse. Additionally, claim 11 has been canceled, thus rendering the rejection of this claim moot.

For a proper rejection of a claim under 35 U.S.C. §102, the cited reference must disclose, teach, or suggest all elements/features of the claim at issue. *See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988). Claim 1 has been amended to recite the following: "wherein the pyrophosphate-type compound includes a substituent that is selected from at least one of: (i) hydrogen, (ii) a cation selected from at least one of lithium, sodium, potassium, calcium, magnesium, chromium, manganese, zinc, and (iii) a functional group that is ionically bonded to or in free association with oxygen of the pyrophosphate." This feature is not taught or suggested by *Gupta*. Instead, *Gupta* employs ferric pyrophosphate in its disclosed dialysate. *Gupta*, *passim*. Nothing in *Gupta* teaches or suggests using a pyrophosphate-type compound that includes one of the substituents

recited in amended independent claim 1. Therefore, claim 1 is novel in view of *Gupta*, and the rejection of claim 1 should be withdrawn.

If independent claim 1 is allowable over the prior art of record, then its dependent claims 5 and 11-13 are allowable as a matter of law, because these dependent claims contain all features/elements/steps of claim 1. *See In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

In addition to foregoing reason for allowability, claim13 recites the feature of "the pyrophosphate-type compound is administered to the human in a dialysate at a concentration from about 3 μM to about 5 μM." The Examiner maintains the contention that "1.6 μM is about 3 μM." Applicants disagree and direct the Office to the decision of *Ortho-McNeil Pharm. v. Caraco Pharm.*, 476 F.3d 1321 (Fed. Cir. 2007), in which the Federal Circuit addressed the meaning of "about" in the patent at issue.

The specification in the patent at issue in *Ortho* disclosed "nested" ranges of ratios, using the term "about", stating:

> the ratio . . . is preferably from about 1:5 to 1:1600; and more preferably, from about 1:19 to 1:800.
>
> The most preferred ratios are from about 1:19 to 1:50. . . . In addition, the particular compositions wherein the ratio of the components are [sic] about 1:1 and about 1:5 are encompassed by the present invention.

Ortho at (quoting U.S. Pat. No. 5,336,691 at col. 3, l. 63 to col. 4, l.8). The court in *Ortho* then concluded that "[t]hese paragraphs suggest that the qualifier 'about' is narrow because to find otherwise would allow the scope of the more specifically identified ratio, 1:5, to encompass a range of ratios that could potentially render meaningless another claim's limitation, namely the 1:1 limitation." That is the exact situation with the present claims. In claims 11 and 12, Applicants claim ranges that

encompass 1.6 μM. In claim 13, however, the claim leaves out a range that would incorporate 1.6 μM. Thus, through the claim vitiation, Applicants do not admit that 1.6 μM of claim 13 is about 3 μM.

Moreover, the court in *Ortho* also stated that "the patentees chose to specifically claim ratios of 1:1 and 1:5. . . . [T]hey could easily have claimed a ratio range of 'about 1:1 to about 1:5,' or even a ratio range of 'about 1:3 to about 1:5,' but they did not. Instead, they chose a specific data point for claim 6 of precisely 1:5. . . . This dichotomy between the specific ratio of 1:5 and the broader ratio ranges of the other claims points to a narrow scope for the 'about 1:5' limitation." Similarly, in the instant case, the broader ranges of other claims supports a narrow scope for the range recited in claim 13. Thus, the rejection of claim 13 should be withdrawn for these reasons as well.

Claim Rejections – 35 U.S.C. § 103

(a) Claims 1, 5, 9, 11-14, and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over *Gupta* and *Russell et al.* (The Journal of Clinical Investigation 1971, 50, 961-969, hereinafter "*Russell*"). Applicants respectfully traverse. Applicants note that the subject matter of claim 10, which has not been rejected based on the combination of *Gupta* and *Russell*, has been incorporated into amended claim 1. Therefore, this rejection should be withdrawn.

(b) Claims 1-4 and 9-10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over *Gupta* and *Sommer* (a text of inorganic chemistry, Herbert Hayward, 1906, hereinafter "*Sommer*"). Applicants respectfully traverse. Additionally, claim 10

has been canceled, thus rendering the rejection of this claim moot. Applicants note that the subject matter of claim 11, which has not been rejected based on the combination of *Gupta* and *Sommer*, has been incorporated into amended claim 1. Therefore, this rejection should be withdrawn.

Moreover, claim 1 is allowable over the combination of *Gupta* and *Sommer*, even without the addition of the subject matter of claim 11. A *prima facie* case of obviousness is established when the teachings from the prior art itself would have suggested the claimed subject matter to a person of ordinary skill in the art. *See In re Rhinehart*, 531 F.2d 1048, 1051 (CCPA 1976). More specifically, the requirements for establishing a *prima facie* case of obviousness include: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See Manual of Patent Examining Procedure* (MPEP) §2143.

In the instant case, there is nothing in the references or in the knowledge generally available to one of ordinary skill in the art to combine the sodium pyrophosphate disclosed in *Sommer* with the ferric pyrophosphate in the dialysate of *Gupta* to arrive at the claimed step of inhibiting vascular calcification. Indeed, according to the disclosure of *Gupta*, there is no need to add sodium pyrophosphate to its disclosed dialysis solution in order to render the ferric pyrophosphate soluble because *Gupta* teaches that soluble ferric pyrophosphate is commercially available and directs the reader to where it can be purchased: "[f]erric pyrophosphate complexed with sodium citrate is soluble in aqueous solutions (ferric pyrophosphate soluble;

Mallinckrodt Inc., St. Louis, MO, USA)." *Gupta* at 1892, col. 2. Thus, nothing in the disclosure of *Gupta* would motivate one of skill in the art to look elsewhere to find compositions to render the ferric pyrophosphate soluble, and thus one would not be motivated to look to the disclosure of *Sommer*. In addition, there is no reasonable expectation of success in combining the two references because the ferric pyrophosphate of *Gupta* is already soluble in the dialysis solution and is already complexed with the sodium citrate. Thus there is no need to add the sodium pyrophosphate disclosed in *Sommer*. Because there is no motivation to combine the references or to a reasonable expectation of success in doing so, the combination of references do not establish a *prima facie* case of obviousness.

If independent claim 1 is allowable over the prior art of record, then its respective dependent claims 2-4 and 9 are allowable as a matter of law, because these dependent claims contain all features/elements/steps of their respective independent claim. *See In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Additionally and notwithstanding the foregoing reasons for the allowability of claim 1, these dependent claims recite further features/steps and/or combinations of features/steps (as apparent by examination of the claims themselves) that are patentably distinct from the prior art of record. Hence, there may be other reasons why these dependent claims are not rendered obvious by the combination of *Gupta* and *Sommer*.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Further, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known for at least the specific and particular reason that the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,

Cynthia J. Lee
Registration No. 46,033

THOMAS, KAYDEN,
HORSTEMEYER & RISLEY, L.L.P.
Suite 1500
600 Galleria Parkway, SE
Atlanta, Georgia 30339
(770) 933-9500

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